



3. Defendant, HOWMEDICA OSTEONICS CORPORATION. d/b/a STRYKER ORTHOPAEDICS (hereinafter “Howmedica”) is a New Jersey Corporation with its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430. At all times material hereto, this Defendant was in the business of designing, manufacturing, promoting, marketing, developing, supplying, labeling, testing, selling and/or distributing orthopedic implants including Accolade hip implants and related components, which includes the LFIT V40 Cobalt Chromium Femoral Head.

4. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds \$75,000, exclusive of interest and cost, and because, among other reasons, Defendant has significant contracts with this District by virtue of doing business within this judicial District.

5. Venue in this action properly lies within this District pursuant to 28 U.S.C. § 1391 because Defendant resides in this District and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this District.

#### **STRYKER ACCOLADE HIP SYSTEM - THE PRODUCT**

6. In March 2000, Stryker released its Accolade TMZF Hip Stem, the latest evolution in the Company's Meridian Titanium Femoral Stem, the Howmedica Asymmetric Stem Femoral Component, the Osteonics Omnifit AD-HA Hip Stem Series, and the Biomet Taperloc Hip Stem, which were all approved for market between the years of 1994 and 1997.

7. According to Stryker's materials, the Accolade TMZF Hip Stem was developed

to maximize a patient's hip range of motion, increase stability, and resist dislocation. These materials also state that the Accolade TMZF Hip Stem is designed to be used with V40 Femoral Heads, which are offered in both forged Vitallium alloy “(CoCr)” and zirconia ceramic. The Accolade Stem is also designed with two neck angles, the standard 132 degrees and extended 127 degrees offset, to assist with joint stability and proper restoration of joint kinematics without lengthening the leg. The neck lengths are proportional relative to the patient's body geometry to accommodate a wider patient population using a standard femoral head.

8. The Accolade TMZF Hip Stem combines the material characteristics of TMZF “(Ti-12Mo-6Zr-2Fe)” with a plasma sprayed coating PureFix HA. The femoral head that is commonly used with the Accolade TMZF Hip Stem is the LFIT Anatomic V40 Femoral Head, which is made from CoCr. Stryker claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

9. Despite Stryker's claims, this material combination has been reported to cause corrosion. For decades, scientists have reported the occurrence of significant fretting and corrosion issues when dissimilar metals are combined. In its marketing and sale of the device, Stryker represented and warranted that its proprietary materials alleviate this problem.

10. In 2012, Stryker recalled its Rejuvenate and ABG II modular hip systems. These two systems employed the same TMZF titanium metal in the femoral stem. The modular neck of both devices was manufactured from CoCr. These devices were recalled after reports surfaced indicating device failure due to fretting and corrosion at the taper junction where these dissimilar metals were joined.

11. Coincidentally, at or about the same time the recall of the Stryker Rejuvenate and ABGII Stems was initiated, Stryker redesigned its Accolade stem. Stryker abandoned use of TMZF titanium and instead its new Accolade II stem is manufactured from a different titanium alloy.

12. On August 29, 2016, Stryker initiated and ultimately issued an involuntary recall of the LFIT Anatomic CoCr V40 Femoral Head stating that Stryker “has received higher than expected complaints of taper lock failure” which may result in potential hazards which include, but may not be limited to, dissociation of femoral head from hip stem; fractured hip stem trunnion, excessive metallic debris, insufficient ROM, insufficient soft tissue tension, noise, loss of implant: bone fixation strength, excessive wear debris (polymeric), implant construct with a shortened neck length.

#### **PLAINTIFF’S USE OF THE PRODUCT**

13. On April 10, 2006, Plaintiff, DAVID T. STEWART, was implanted with an Accolade TMZF Plus Stem 127° neck angle with a 36 mm +5 offset CoCr LFIT V40 femoral head on his right hip by Dr. Anthony M. Digioia at UPMC Health System in Pittsburgh, Pennsylvania. The components at issue were designed and manufactured, distributed, marketed and sold by Defendant Howmedica.

14. After the implantation of the Accolade® Hip System, in 2016 Plaintiff DAVID T. STEWART began experiencing significant pain and discomfort in the area of the subject device.

15. Initial workup revealed the absence of infection, malposition, as the explanation of the Plaintiff’s symptoms.

16. On July 7, 2016, further diagnostic workup revealed the presence of increased levels of metal ions in the blood, specifically Cobalt – 1.6 mcg/L; Chromium 2.2 mcg/L; and Titanium 77 mcg/L with a reporting limit of 10 mcg/L.

17. On October 15, 2016, Plaintiff attempted to get out of a seated position from his chair and had pain with the inability to move his hip. As a result, Plaintiff presented to the Emergency Department.

18. Based upon these findings, revision surgery of the Plaintiff's right hip was scheduled for and completed on October 18, 2016 at UPMC Health System by Dr. Kenneth Urish, M.D. During that surgery, Dr. Urish observed, among other things, the presence of a large black pseudotumor and a large amount of black metallic debris within the pseudotumor. His surgeon also noted the presence of gross trunnion failure between the Accolade stem and Stryker's LFIT V40 CoCr femoral head.

19. Subsequent to the revision surgery, Plaintiff is undergoing extensive rehabilitation of the revised hip.

## **CAUSES OF ACTION**

### **COUNT I**

#### **STRICT PRODUCTS LIABILITY-DESIGN DEFECT**

19. Plaintiff DAVID T. STEWART adopts by reference all of the allegations contained in Paragraphs 1 through 19 above, each inclusive, as though fully set forth.

20. Defendant HOWMEDICA has engaged in the for profit business of selling,

distributing, supplying, designing, manufacturing, marketing and/or promoting Accolade® Hip System and related components each defective and unreasonably dangerous to consumers, including Plaintiff, when placed in the stream of commerce.

21. The Accolade® Hip System and related components sold, distributed, supplied, designed, manufactured and/or promoted by Defendant HOWMEDICA's were each expected to reach, and did reach consumers, including Plaintiff's Physician and Plaintiff, without substantial change in the defective condition in which they were in when they left Defendant HOWMEDICA's possession.

22. The Accolade® Hip System and related components were unreasonably dangerous by virtue of design defects and were not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the device.

23. The Accolade® Hip System and related components were unreasonably dangerous by virtue of design defects where Defendant HOWMEDICA failed to adequately design and manufacture the device to insure that it would not corrode, erode, deteriorate, and/or induce severe metal toxicity in the patient. The flaws include, but are not limited to:

- a) Incompatibility of the TMZF titanium alloy with other device components;
- b) Poor design of the taper neck junction between stem and neck, such that micro-motion was predictable;
- c) Poor design of manufacturing practices such that the taper neck junction between the neck and stem do not "fit" the way they were intended;
- d) And, a combination of the above factors leads to rapid, severe heavy metal cast-off causing soft tissue and bony necrosis, pain and premature failure of the

device;

e) Defendant HOWMEDICA failed to adequately test the TMZF alloy's compatibility with chrome cobalt components to prevent corrosion and fretting at the neck/stem taper neck junction of the Accolade® Hip System ;

f) Defendant HOWMEDICA chose as its predicate device a hip implant system that had known failures in the past; had to be redesigned due to design flaws; and has been the subject of protracted litigation filed by patients harmed by defects in the predicate modular device.

24. The Accolade® Hip System and related components were defective in design and formulation – as set forth more fully in the preceding paragraph - where Defendant HOWMEDICA's Accolade® Hip System does not perform as safely as an ordinary consumer, such as Plaintiff's Physician and Plaintiff, would expect when used as intended or in a manner reasonably foreseeable to Defendant HOWMEDICA making use of the device more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with non-use or alternate products.

25. Defendant HOWMEDICA's Accolade® Hip System is designed in such a way that, when used as intended, it causes foreseeable serious, permanent, and devastating damage to patients in whom the devices are implanted from corrosion, erosion, deterioration, and severe metal toxicity. Defendant HOWMEDICA acted unreasonably in its design of the Accolade® Hip System because Defendant HOWMEDICA failed to adopt a safer design for the Accolade® Hip System that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality or desirability of the product.

26. There were numerous safer alternative designs accessible and available to the Accolade® Hip System which in reasonable probability would have prevented or significantly reduced the foreseeable risk of the personal injuries suffered by Plaintiff herein without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible when the Accolade® Hip System left the control of Defendant HOWMEDICA by the application of existing or reasonably achievable scientific knowledge.

27. The risks of using Defendant HOWMEDICA's Accolade® Hip System outweigh the benefits of using the device.

28. The Accolade® Hip System and its related components were not safe for their intended use as orthopedic hip implants and were inadequately tested.

29. Plaintiff's Physician and Plaintiff DAVID T. STEWART used the Accolade® Hip System and related components for their intended purpose, i.e. for joint replacement, total hip arthroplasty.

30. Neither Plaintiff nor Plaintiff's Physician could have discovered any defect in the Accolade® Hip System through the exercise of due care.

31. Defendant HOWMEDICA as manufacturer and distributor of a medical device, are held to the level of knowledge of an expert in their field.

32. Plaintiff and Plaintiff's Physician did not have substantially the same knowledge as Defendant HOWMEDICA, as an adequate warning from the manufacturer or distributor should have communicated to Plaintiff's Physician. The warnings given by the Defendant



HOWMEDICA were intentionally inaccurate and not complete regarding the safety of the Accolade® Hip System , adequacy of the device design, defective manufacture of the device, defective design of the device, failure rate of the device, and were otherwise inaccurate.

33. As a direct and proximate result of the unreasonably dangerous nature of the Accolade® Hip System, it would not have been implanted in Plaintiff DAVID T. STEWART, used by Plaintiff DAVID T. STEWART or Plaintiff's Physician, and Plaintiff would not have sustained the foreseeable injuries alleged herein.

34. As a direct and proximate result of the defective and unreasonably dangerous condition of the product as described above, Plaintiff DAVID T. STEWART was injured in and about Plaintiff DAVID T. STEWART's body or suffered an aggravation of a pre-existing condition or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of injuries, suffered physical handicap, suffered psychological and emotional injuries, suffered loss of wages and/or impairment to working ability, sustained permanent injuries within a reasonable degree of medical probability and/or suffered permanent loss of an important bodily function, has lost or suffered permanent impairment of the capacity for the enjoyment of life, and has a continuing fear of contracting additional sequela of unsafe metal exposure.

35. Because the injuries suffered by Plaintiff are continuing in nature, Plaintiff will continue to suffer pain, psychological, and emotional injuries, physical handicap and permanent injury in the future, loss of wages and earning capacity, will be further compelled to expend great sums of money for medical care and related treatment for the injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

**COUNT II**  
**STRICT PRODUCTS LIABILITY - FAILURE TO WARN**

36. Plaintiff DAVID T. STEWART adopts by reference all of the allegations in Paragraphs 1 through 19 above, each inclusive, as though fully set forth.

37. At all times material hereto, Defendant HOWMEDICA, the device manufacturer and distributor, and sales representatives individually and collectively, have engaged in the for profit business of selling, designing, distributing, supplying, manufacturing, marketing and/or promoting the Accolade® Hip System and related components, along with their sales and promotional materials, that were each defective and unreasonably dangerous to consumers, including the Plaintiff's Physician and Plaintiff.

38. The Accolade® Hip System and related components sold, designed, distributed, supplied, manufactured and/or promoted by Defendant HOWMEDICA, individually and collectively, with their sales and promotional materials, were each expected to reach, and reached consumers, including Plaintiff's Physician and Plaintiff, without substantial change in the condition from when they left Defendant's possession.

39. The Accolade® Hip System and related components sold, designed, distributed, supplied, manufactured and/or promoted by the Defendant device manufacturer, distributors, and sales representatives, with their sales and promotional materials, individually and collectively, were each in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce by virtue of the lack of adequate and accurate warnings as described in

the following paragraphs. The warnings were inadequate and inaccurate.

40. The Accolade® Hip System and related components were unreasonably dangerous and were not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the device.

41. Defendant device manufacturer, distributor and sales representatives had a continuing duty to warn Plaintiff's Physician of the dangers, material defects and inadequacies associated with the Accolade® Hip System .

42. The Accolade® Hip System were unreasonably dangerous where Defendant failed to adequately warn consumers including Plaintiff's Physician that the Accolade® Hip System implanted into Plaintiff herein contained no warnings or inadequate warnings on the risks that the Accolade® Hip System could cause fretting, corrosion, and significant heavy metal toxicity.

43. The Accolade® Hip System was also defective and unreasonably dangerous because:

- a) Defendant HOWMEDICA failed to warn that the Accolade® Hip System would corrode, erode, deteriorate, and induce severe metal toxicity in the patient. The flaws include but are not limited to: incompatibility of the TMZF titanium alloy with other device components; poor design of the taper neck junction between stem and neck, such that micro-motion was predictable; poor manufacturing practices such that the taper neck junction between the neck and stem do not "fit" the way they were intended; and a combination of the above factors leads to rapid, severe heavy metal cast-off causing damaging metal exposure, soft tissue and bony necrosis, pain, and premature failure of the device.
- b) Defendant HOWMEDICA failed to adequately warn the Accolade® Hip System was not tested to insure that it would not corrode, erode, deteriorate and/or induce severe metal toxicity in the patients, like the DAVID T. STEWART;

- c) Defendant HOWMEDICA failed to adequately warn that the Accolade® Hip System had undergone only bench testing so that when manufactured and marketed, the patients became Defendant's first clinical trial;
- d) Defendant HOWMEDICA inadequately warned by making affirmative representations that the Accolade® Hip System would not fret or corrode in the human body. These representations were false and misleading to consumers, including to Plaintiff's Physician;
- e) Defendant HOWMEDICA inadequately warned where Defendant made affirmative representations regarding the failure rate, interval and frequency of the Accolade® Hip System. These representations were false and misleading to physicians, including Plaintiff's implanting Physician;
- f) Defendant HOWMEDICA inadequately warned where Defendant trained its sales force to detail the Accolade® Hip System utilizing representations that Defendant knew or should have known were false, creating in the minds of surgeons, including Plaintiff's Physician, that the Accolade® Hip System would not cause metal toxicity and would not prematurely fail;
- g) Defendant HOWMEDICA inadequately warned where Defendant specifically marketed and promoted the Accolade® Hip System as a safe alternative to metal-on-metal bearing surface devices widely publicized as capable of causing premature failure due to heavy metal toxicity, which was false and inaccurate;
- h) Defendant HOWMEDICA inadequately warned where Defendant falsely and inaccurately marketed the Accolade® Hip System as a "perfect fit" for younger patients due to its modular design, creating in the minds of physicians, including Plaintiff's Physician, that the Accolade® Hip System was superior to other available hip implants.
- i) Defendant HOWMEDICA inadequately warned where it failed to promptly act upon and warn of reports of early failure, such that the Accolade® Hip System continued to be implanted in unknowing patients by unknowing surgeons well after it should have been recalled or sales suspended;
- j) Defendant HOWMEDICA inadequately warned that Defendant had actual knowledge prior to marketing the Accolade® Hip Systems that its TMZF titanium alloy performed poorly when mated with chrome cobalt components. Defendant also knew when it introduced the Accolade® Hip System to the market that the Stryker Accolade (and other Stryker devices also made of TMZF alloy) was

experiencing corrosion, fretting, and failure issues at the taper neck junction between the neck and chrome cobalt head or ball. Defendant either suppressed or ignored these reports and marketed the Accolade® Hip System anyway, knowing these two dissimilar metals when utilized in various hip implant devices were performing poorly in the market and causing harm to patients.

k) Defendant HOWMEDICA inadequately warned where Defendant's device distributors and sellers, in continuing to manufacture, create, design, test, label, sterilize, package, supply, market, sell, advertise, warn, promote and/or otherwise distribute the Accolade® Hip System in interstate commerce, while failing to warn Plaintiff's Physician of the dangers of the Accolade® Hip System, negligently misrepresented that the Accolade® Hip System were fit for use, merchantable and reasonably safe for their intended purpose.

44. Defendant HOWMEDICA as manufacturer and distributor of a medical device, is held to the level of knowledge of an expert in their field and knew or should have known - in light of the best and generally recognized scientific knowledge during the time of manufacture - of the above described facts and conditions as set forth in the preceding paragraphs.

45. The warnings that accompanied the Accolade® Hip System failed to provide that level of information that an ordinary consumer, including Plaintiff's Physician, would expect when using the implants in a manner reasonably foreseeable to the Defendant. The Accolade® Hip System left to the Defendant HOWMEDICA's control without an adequate warning or instruction, and created an unreasonably dangerous condition in that Defendant HOWMEDICA, as the seller and manufacturer, knew or in exercising ordinary care should have known that the Accolade® Hip System posed a substantial risk of harm. Alternatively, after the Accolade® Hip System left the Defendant HOWMEDICA's control, Defendant learned of, or in exercising ordinary care should have known, that the Accolade® Hip System posed a substantial risk of harm to patients, including Plaintiff, yet Defendant HOWMEDICA failed to give adequate

warning or instruction or to take other reasonable action under the circumstances, including an earlier recall of the product.

46. The Accolade® Hip System and related components warnings were inadequate and it was defective in design and formulation where there were no warnings, of erosion, corrosion, deterioration, premature failure and severe metal toxicity, and where Defendant HOWMEDICA's Accolade® Hip System does not perform as safely as an ordinary consumer, such as Plaintiff's Physician, would expect when used as intended or in a manner reasonably foreseeable to Defendant HOWMEDICA, making use of the Accolade® Hip System more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with non-use or available reasonable alternative designs.

47. There were numerous safer alternative designs to the Accolade® Hip System which in reasonable probability would have prevented or significantly reduced the risk of the foreseeable personal injuries suffered by Plaintiff without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the Accolade® Hip System left the control of Defendant by applying existing or reasonably achievable scientific knowledge.

48. The risks of using Defendant HOWMEDICA's Accolade® Hip System outweigh the benefits or utility of using the devices.

49. Plaintiff DAVID T. STEWART and Plaintiff's Physician used the Accolade® Hip System and related components for their intended purpose as marketed and promoted by Defendant, i.e. for joint replacement, or total hip arthroplasty.

50. Plaintiff's Physician could not have discovered the inadequacy of warning through the exercise of due care.

51. Plaintiff and Plaintiff's Physician did not have substantially the same knowledge as Defendant HOWMEDICA, as an adequate warning from the manufacturer or distributor should have communicated to Plaintiff's Physician. Therefore, Defendant HOWMEDICA should have communicated such knowledge to the Plaintiff's Physician.

52. Had Defendant HOWMEDICA provided adequate warnings, the Accolade® Hip System and related components would not have been implanted in Plaintiff DAVID T. STEWART, used by Plaintiff DAVID T. STEWART or Plaintiff's Physician, and Plaintiff would not have sustained the injuries alleged. Had Plaintiff and Plaintiff's Physicians received a proper or adequate warning on the risks associated with using the Accolade® Hip System, Plaintiff's Physicians would not have recommended the Accolade® Hip System; would have used an alternate device; or, at a minimum, would have provided Plaintiff with adequate warnings and obtained informed consent.

53. As a direct and proximate result of the unreasonably dangerous condition of the Accolade® Hip System by inadequate, inaccurate and incomplete warnings as described above, Plaintiff DAVID T. STEWART was injured in and about Plaintiff DAVID T. STEWART's body or suffered the aggravation a pre-existing condition or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of injuries, suffered physical handicap, suffered psychological and emotional injuries, suffered loss of wages and/or impairment to working ability, sustained permanent injuries within a reasonable degree of medical probability and/or

suffered permanent loss of an important bodily function, has lost or suffered permanent impairment of the capacity for the enjoyment of life, and has a continuing fear of contracting additional sequelae of unsafe metal exposure all of which were foreseeable by Defendant.

54. Because the injuries suffered by Plaintiff are continuing, Plaintiff will continue to suffer pain, psychological and emotional injuries, physical handicap and permanent injury in the future, loss of wages and earning capacity, will be further compelled to expend great sums of money for medical care and related treatment for the injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

**COUNT III**  
**STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

55. Plaintiff DAVID T. STEWART adopts by reference all of the allegations contained in Paragraphs 1 through 19 above, each inclusive, as though fully set forth.

56. This is an action for strict liability based on a manufacturing defect.

57. The Accolade® Hip System is designed for implantation into the human body and to last for fifteen or more years. The Accolade® Hip System was also designed to be compatible with human tissue and bone; and, to be free from corrosion, erosion, metal ion cast-off and deterioration.

58. The Accolade® Hip System and related components installed in the hip of Plaintiff DAVID T. STEWART herein were not compatible with human tissue and bone. Through fretting and corrosion, the Accolade® Hip System released heavy metals into the body of Plaintiff DAVID T. STEWART herein causing severe and permanent destruction of bone and



tissue.

59. The Accolade® Hip System is unreasonably dangerous where Defendant HOWMEDICA failed to manufacture the Accolade® Hip System to prevent fretting and corrosion, and manufactured the product such that it caused fretting and corrosion.

60. The Accolade® Hip System is unreasonably dangerous where Defendant HOWMEDICA failed to manufacture the Accolade® Hip System in a manner that the components of the device fit properly together to prevent micro-motion in the Accolade® Hip System .

61. The Accolade® Hip System is unreasonably dangerous where Defendant HOWMEDICA failed to manufacture the Accolade® Hip System and related components to industry standards and Defendant HOWMEDICA's own specifications such that the taper neck junction between the neck and stem prematurely failed causing metal debris cast off and severe metal toxicity in patients including Plaintiff DAVID T. STEWART.

62. The Accolade® Hip System and related components were not safe for their intended use as orthopedic hip implants.

63. Plaintiff DAVID T. STEWART and Plaintiff's Physician used the Accolade® Hip System and related components for their intended purpose, i.e. for joint replacement, total hip arthroplasty.

64. Neither Plaintiff nor Plaintiff's Physician, could have discovered the aforesaid manufacturing defects through exercising due care.

65. Defendant HOWMEDICA, as manufacturer of a medical device, is held to the

level of knowledge of an expert in their field.

66. Plaintiff and Plaintiff's Physician, did not have knowledge of the manufacturing defects.

67. As a direct and proximate result of the manufacturing defects as described above, Plaintiff DAVID T. STEWART was injured in and about Plaintiff DAVID T. STEWART's body or suffered the aggravation of a pre-existing condition or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of his injuries, suffered physical handicap, suffered psychological and emotional injuries, suffered loss of wages and/or impairment to his working ability, sustained permanent injuries within a reasonable degree of medical probability and/or suffered permanent loss of an important bodily function, has lost or suffered permanent impairment of the capacity for the enjoyment of life, and has a continuing fear of contracting additional sequelae of unsafe metal exposure all of which were a foreseeable result of the manufacturing defects and unreasonably dangerous condition of the product.

68. In that the injuries suffered by Plaintiff are continuing, Plaintiff will continue to suffer pain, psychological and emotional injuries, physical handicap and permanent injury in the future, loss of wages and earning capacity, will be further compelled to expend great sums of money for medical care and related treatment for the injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

**COUNT IV**  
**NEGLIGENCE**

69. Plaintiff DAVID T. STEWART adopts by reference all of the allegations

contained in Paragraphs 1 through 19 above, each inclusive, as though fully set forth.

70. At all times relevant hereto, Defendant HOWMEDICA designed, manufactured, distributed, sold, marketed, and/or promoted the Accolade® Hip System for implantation into individuals, such as Plaintiff DAVID T. STEWART, by physicians and surgeons in the United States.

71. Defendant HOWMEDICA as the device designer, manufacturer, distributor, and seller, owed a duty to the expected consumers of their product, including the Plaintiff's Physician and Plaintiff, to exercise reasonable care in the design, manufacture, sale, promotion and/or distribution of the Accolade® Hip System when placed into the stream of commerce.

72. Defendant HOWMEDICA owed an additional and further duty to provide adequate and complete instructions and warnings to the implanting physicians and consumers of the Accolade® Hip System and related components, and to promptly amend and supplement such instructions and warnings upon the discovery of information necessitating such amendment and supplement.

73. Defendant HOWMEDICA had a duty to perform each of these functions with reasonable and due care for the safety and well-being of patients in whom the Accolade® Hip System would be implanted, including Plaintiff DAVID T. STEWART.

74. Defendant HOWMEDICA was careless and negligent and breached the aforementioned duties in ways which include, but are not limited to, one or more of the following:

- a) Defendant HOWMEDICA failed to adequately design and manufacture the Accolade® Hip System to insure that it would not corrode, erode, deteriorate and

induce severe metal toxicity in the patient. The flaws include but are not limited to: incompatibility of the TMZF titanium alloy with other device components; poor design of the taper neck junction between stem and neck, such that micro-motion was predictable; poor manufacturing practices such that the taper neck junction between the neck and stem do not “fit” the way they were intended; and a combination of the above factors leads to rapid, severe heavy metal cast-off causing damaging metal exposure, soft tissue and bony necrosis, pain, and premature failure of the device;

b) Defendant HOWMEDICA failed to adequately test the Accolade® Hip System to insure that it would not corrode, erode, deteriorate and/or induce severe metal toxicity in the patients, where performance of such tests would have been practical and would have revealed the design defects with the product;

c) Defendant HOWMEDICA failed to conduct anything other than bench testing so that when manufactured and marketed, the patients became Defendant HOWMEDICA’s first clinical trial;

d) During the time Defendant HOWMEDICA marketed these products, Defendant HOWMEDICA made repeated affirmative representations to Plaintiff’s Physician and Plaintiff that the Accolade® Hip System would not fret or corrode in the human body.

e) During the time the Defendant marketed these products, Defendant made repeated affirmative representations regarding the failure rate of the Accolade® Hip System . These representations were inaccurate, false and misleading to both physicians and patients, including Plaintiff’s Physician and Plaintiff;

f) Defendant HOWMEDICA trained their sales force and agents to detail the Accolade® Hip System utilizing representations that Defendant HOWMEDICA knew or should have known were false, creating in the minds of both surgeons and consumers, including Plaintiff, that the Accolade® Hip System would not cause metal toxicity and would not prematurely fail;

g) Defendant HOWMEDICA specifically marketed the Accolade® Hip System as a safe alternative to metal-on-metal bearing surface devices widely publicized as capable of causing premature failure due to heavy metal toxicity, which was false and inaccurate;

h) Defendant HOWMEDICA failed to manufacture the product to reasonable

industry standards and Defendant HOWMEDICA's own internal specifications, such that the taper neck junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients and premature failure;

i) Defendant HOWMEDICA failed to adequately test the TMZF alloy's compatibility with chrome cobalt components to prevent corrosion and fretting at the neck/stem taper neck junction of the Accolade® Hip System where performance of such tests would have been practical and would have revealed the design defects with the product;

j) Defendant HOWMEDICA failed to promptly act upon reports of early failure, such that the Accolade® Hip System continued to be implanted in unknowing patients by unknowing surgeons well after it should have been recalled or sales suspended;

k) Defendant HOWMEDICA chose as its predicate device a modular hip implant system that had known failures in the past; had to be redesigned due to design flaws; and has been the subject of protracted litigation filed by patients harmed by defects in the predicate modular device;

l) Defendant HOWMEDICA had actual notice with knowledge prior to marketing the Accolade® Hip System that its TMZF titanium alloy performed poorly when mated with chrome cobalt components. Defendant HOWMEDICA also knew when it introduced the Accolade® Hip System to the market that the Stryker Accolade (and other Stryker devices also made of TMZF alloy) was experiencing corrosion, fretting and failure issues at the taper neck junction between the neck and chrome cobalt head or ball. Defendant HOWMEDICA either suppressed or ignored these reports and marketed the Accolade® Hip System anyway, knowing these two dissimilar metals when utilized in various hip implant devices were performing poorly in the market and causing harm to patients;

m) Defendant HOWMEDICA while continuing to manufacture, create, design, test, label, sterilize, package, supply, market, sell, advertise, promote and/or otherwise distribute the Accolade® Hip System in interstate commerce, failed to warn Plaintiff's Physician and Plaintiff of the dangers of the Accolade® Hip System and negligently misrepresented that the Accolade® Hip System were fit for use, merchantable and reasonably safe for their intended purpose.

75. The aforementioned negligent misrepresentations were material and made by Defendant HOWMEDICA with the intention that Plaintiff's Physician and Plaintiff would act and rely upon them. And, Defendant HOWMEDICA either knew, or should have known, that the representations were false, misleading, or inaccurate.

76. Defendant HOWMEDICA could have avoided the defective nature of the product design through the adoption of available reasonably safe alternative design and omission of such rendered the product unsafe and unreasonably dangerous.

77. Defendant HOWMEDICA as a manufacturer, designer and distributor, are held to the level of knowledge of an expert in their field. Defendant HOWMEDICA had, knew, or, in light of the best and generally recognized scientific knowledge during the time of manufacture, should have known that its representations were inaccurate and untrue and this was unknown and unforeseen by Plaintiff's Physician and Plaintiff.

78. Plaintiff's Physician and Plaintiff did not have substantially the same knowledge, as an adequate warning from the designer, manufacturer and/or distributor and such should have been communicated to Plaintiff's Physician. The warnings given by Defendant HOWMEDICA were inaccurate and not complete regarding the safety of the Accolade® Hip System , adequacy of the device design, defective manufacture of the device, defective design of the device, failure rate of the device and were otherwise inaccurate.

79. Plaintiff's Physician and Plaintiff acted in justifiable reliance on Defendant

HOWMEDICA's statements by implanting the defective Accolade® Hip System in Plaintiff.

80. As a direct and proximate result of the unreasonably dangerous nature of the negligent acts and omissions of Defendant HOWMEDICA, the Accolade® Hip System and related components would not have been implanted in Plaintiff DAVID T. STEWART, used by Plaintiff DAVID T. STEWART or Plaintiff's Physician, and Plaintiff would not have sustained the injuries alleged herein.

81. It was foreseeable that a breach of the aforementioned duties would cause injury and/or related damage to the ultimate consumers of the Accolade® Hip System, including the Plaintiff. It was foreseeable that such negligence would lead to the conditions described herein and premature device failure and severe, permanent, debilitating injury to patients, including Plaintiff herein.

82. As a direct, legal, proximate and producing result of the Defendant's negligent design, testing, manufacturing, marketing, selling, and promoting of the Accolade® Hip System as described above, Plaintiff DAVID T. STEWART was injured in and about Plaintiff DAVID T. STEWART's body or suffered the aggravation of a pre-existing condition or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of his injuries, suffered physical handicap, suffered psychological and emotional injuries, suffered loss of wages and/or impairment to working ability, sustained permanent injuries within a reasonable degree of medical probability and/or suffered permanent loss of an important bodily function, has lost or suffered permanent impairment of the capacity for the enjoyment of life, and has a continuing fear of contracting additional sequela of unsafe metal exposure.

83. The injuries suffered by Plaintiff are continuing in nature, Plaintiff will continue to suffer pain, psychological and emotional injuries, physical handicap and permanent injury in the future, loss of wages and earning capacity, will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss or impairment of the capacity for the enjoyment of life.

84. Defendant's negligent design, testing, manufacturing, marketing, selling and promoting of the Accolade® Hip System implanted in Plaintiff DAVID T. STEWART was a substantial factor in Plaintiff's injuries as set forth above.

**COUNT V**  
**BREACH OF EXPRESS WARRANTY**

85. Plaintiff DAVID T. STEWART adopts by reference all of the allegations contained in Paragraphs 1 through 19 above, each inclusive, as though fully set forth.

86. Through their public statements, their descriptions of the Accolade® Hip System and their promises relating to the Accolade® Hip System, Defendant expressly warranted among other things that the Accolade® Hip System was efficacious and safe for its intended use and was designed and constructed of materials that would prevent fretting and corrosion and would provide superior component longevity that competing products.

87. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Accolade® Hip System, but which contained material misrepresentations and utterly failed to warn of the risks of the Accolade®



Hip System; (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the Accolade® Hip System and the downplaying of the risks associated with the Accolade® Hip System; (iv) false and misleading written information supplied by Defendant.

88. Plaintiff further alleges that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendant and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

89. When Defendant made these express warranties, Defendant knew the purpose for which Accolade® Hip System was to be used and warranted it to be in all respects safe and proper for such purpose including its combination with CoCr femoral heads.

90. Defendant drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

91. The Accolade® Hip System does not conform to Defendant's representations in that it is not safe and produces serious side effects when combined with CoCr heads.

92. As such, the Accolade® Hip System did not conform to Defendant's promises, descriptions or affirmations of fact and was not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such devices are used.

93. Defendant therefore breached its express warranties to Plaintiff by manufacturing, marketing and selling the Accolade® Hip System to Plaintiff causing damages

as will be established at trial.

**COUNT VI**  
**BREACH OF IMPLIED WARRANTY**

94. Plaintiff DAVID T. STEWART adopts by reference all of the allegations contained in Paragraphs 1 through 19 above, each inclusive, as though fully set forth.

95. The Accolade® Hip System was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Accolade® Hip System minimally safe for its expected purpose.

96. At all relevant times, Plaintiff used the Accolade® Hip System for the purpose and in the manner intended by Defendant.

97. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

98. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

99. As a direct and proximate result of Defendant's acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Accolade® Hip System, Plaintiff was implanted with Accolade® Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and

equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT VII**  
**LOSS OF CONSORTIUM**

100. Plaintiffs incorporate, by reference, all previous paragraphs as if fully set forth at length herein.

101. As a direct and proximate result of the negligence and carelessness of the Defendants herein, Plaintiff, DONNA STEWART, suffered a loss of the society, comfort, companionship and consortium of her husband, DAVID T. STEWART, and will continue to suffer same for an indefinite time in the future, to her great detriment and loss.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs DAVID T. STEWART and DONNA STEWART, individually and as husband and wife, pray for judgment against the Defendant as follows:

- a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;
- b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation

and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

- c. Loss of the society, comfort, companionship and consortium;
- d. Double or triple damages as allowed by law;
- e. Attorneys' fees, expenses, and costs of this action;
- f. Pre-judgment and post-judgment interest in the maximum amount allowed by law;
- g. Punitive damages; and,
- h. Such further relief as this Court deems necessary, just, and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff DAVID T. STEWART demands a trial by jury on all issues and matters so triable by jury as a matter of right.

Dated: April 28, 2017

**Attorneys for Plaintiff**

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***(Pro hac vice application to be filed)***

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